

**MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
MAY 31, 2012
COEUR D ALENE RESORT – COEUR D ALENE, IDAHO**

This meeting of the Board was held to conduct regular Board business.

Chairman Richard de Blaquiére, Pharm D, called the meeting to order on May 31, 2012 at 8:06 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D.; Holly Henggeler, Pharm D.; Ed Sperry, and Mark Johnston, R.Ph., Executive Director; Jenifer Marcus, DAG; Nicole McKay, DAG; Kathy Takasugi, DAG; Andrew Snook, DAG; Jan Atkinson, Senior Compliance Officer; Fred Collings, Chief CS Investigator; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

The minutes of the April 5, 2012 Board meeting were reviewed. Dr. Chopski motioned to approve the minutes as written. Mr. Fraser seconded. Dr. Henggeler and Mr. Johnston noted minor corrections were needed. Dr. Chopski amended her motion to approve the minutes with minor corrections. Dr. Henggeler seconded. The motion carried unanimously.

Dr. de Blaquiére introduced and welcomed new public Board member, Ed Sperry, to his first Board meeting.

The Negotiated Rule Making Hearing on Non-resident Pharmacy began with Mr. Johnston's explanation of a new statutory requirement for negotiated rule making. The Board will satisfy this requirement by holding hearings at the public Board meetings. Draft language of changes to the Out-of-State Mail Service Pharmacy Act were presented with the goal of having a more polished version by the end of August 2012, in order to present to the Legislature in 2013.

Speakers Chris Ciolko, R.Ph, Senior Vice President, Business Development and David White, Chief Information Officer and Senior Vice President of Operations of Pipeline Healthcare Solutions presented an executive summary to the Board regarding their remote medication order processing business model. Pipeline Healthcare requested registration or licensure of pharmacists, but saw no need for drug outlet registration or licensure. They requested "telepharmacy across state line" practice standards for their services too, as opposed to the current lesser "independent practice of pharmacy" standards. They suggested mandating hiring (not contracting with) of pharmacists who work from home to provide cognitive services to institutions. They also supported audit trail and Board inspection draft rules. They suggested incorporating by reference the American Society of Health-System Pharmacists guidelines into law. Mr. Johnston pointed out that said guidelines were utilized to develop current telepharmacy across state lines practice standards.

Speaker John Jones, R.Ph, J.D., Vice President of Government Affairs and Pharmacy Policy for OptumRx Inc., supported the audit trail draft rule and explained that mail service and central fill are basically the same because such practices occur in the same facility. He supported Verified Internet Pharmacy Practice Sites (VIPPS) accreditation. Mr. Jones explained that a typical nonresident model trusts the home state Board of Pharmacy to discipline and limits the discipline authority of the states that the facility ships to, like Idaho, in order to avoid conflicting state laws. Dr. Henggeler expressed her concern over nonresidents practicing pharmacy into Idaho, while operating under standards that are lower than those required in Idaho. Mr. Jones

did not support the draft requirement of an Idaho licensed Pharmacist in Charge (PIC) for each nonresident drug outlet.

Speaker Richard Palombo, R.Ph., Senior Director of Regulatory Affairs for Express Scripts, supports VIPPS accreditation in place of PIC licensure, but ultimately saw no value in PIC requirements, citing that the only states that require a licensed PIC are Arizona and Georgia. Montana requires a "contact person" which he believed would be a good compromise. Mr. Palombo supported the draft audit trail rule and home state discipline, as Mr. Jones explained, but with an additional contract for compliance such as used in New Jersey, Texas, Illinois and Nevada. Mr. Palombo reported that labeling requirements are 95% the same in all states, so he believed that home state labeling should be the standard to avoid conflicts in law. He supported the New Jersey language defining the four (4) components to central fill and requirements for policy and procedure manuals, as well as statements of purpose. He also cautioned against restricting central fill pharmacies from mailing directly to the patient.

In addition to comments made at the 4/5/12 Board presentation by his coworker, Bill Cover, concerning Walgreens' central fill and processing centers, speaker Al Carter, Corporate Manager, Pharmacy Affairs for Walgreens, supports home state discipline, as previously discussed. In response to the current statute draft, he believed there are too many confusing categories and suggests only one non-resident category, separate from wholesalers and manufacturers. Mr. Carter believed that mail order and central fill are the same thing, but that central processing and central filling are two separate activities.

At the conclusion of the negotiated rule making hearing, Mr. Johnston detailed the challenges before the Board, including:

- The Board registers small mail service operations, such as compounding specialty pharmacies, so law should not be written with only typical, massive mail service pharmacies in mind.
- To harmonize or differentiate mail service Vs central fill?
- Harmonizing current telepharmacy across state lines rules with the independent practice of pharmacy rules, including practicing pharmacy from a secured business location and from a pharmacist's home.
- To harmonize or differentiate institutional cognitive services Vs retail cognitive services and data processing.
- Allow in state activities that are allowed out of state.
- The Boards toughest decisions involve what pharmacists and what facilities in the various practice settings to license, register or neither, including the PIC. Mr. Johnston believes that the Idaho Legislature will not approve across the board licensure for all nonresident pharmacists that practice pharmacy into Idaho, as out-of-state mail service pharmacies will argue that this would increase costs, equating to a decreased number of insured Idahoans, which decreases public safety, contrary to the Board's mission.
- Additional difficult Board decisions involve identifying Idaho practice standards that should be enforced upon nonresidents, considering that such decisions may create conflicts of law. Examples include current substitution and selection law, as well as draft audit trail rules.

The Board directed Mr. Johnston to draft separate rules for each of the non-resident pharmacy practices, and then the process of combining commonalities could commence. Dr. Chopski believed that all Idaho law should be followed by nonresidents. Dr. Henggeler believed that all nonresident pharmacists practicing pharmacy into Idaho should be licensed. Dr. de Blaquiére was concerned with the lack of regulation surrounding common carriers. Mr. Fraser would like to see a break out of each of the various practice settings and what functions they perform.

Dr. de Blaquiére called the meeting back to order after a short break.

H. Stuart Willis III, MD, Director of the Emergency Department for Boundary Community Hospital presented a request for waiver or variance & rule promulgation regarding Institutional Facility/Emergency Outpatient Drug Delivery. During discussions, which included Mr. Brown, the Board determined that rule 637 only pertained to nurses dispensing in the absence of a prescriber in frontier areas, as defined and allowed by the federal government. Thus, the Board determined that prescriber dispensing from a hospital's emergency room was not regulated by rule 637 and that Dr. Willis was not restricted from dispensing schedule II substances. Therefore, no waiver or variance is necessary. Mr. Johnston will research and believes modifications to rule 637 may be needed to clarify.

David Tester, DVM, presented requests for waiver or variance & rule promulgation on behalf of the Idaho Veterinary Medical Association (IVMA). After much discussion, the Board determined:

- Veterinarians are not subject to federal laws concerning the delivery of Medguides.
- Veterinarian injected Rx items that are not required to be prepared in a sterile environment by the manufacturer are not subject to Board rule 240: Sterile Product Preparation.
- A letter thought by IVMA to be prepared by the Board was not prepared by the Board. Said letter contained errors concerning VDO sales, which disrupted the veterinarian community. Mr. Johnston will send a letter later this summer to VDOs clarifying the issues.
- IVMA contends that veterinarians are conducting statutorily mandated prospective drug review and counseling. The Board did not believe that a waiver from the documentation of counseling was appropriate.
- The Board referred IVMA to a recent Idaho Board of Veterinarian Medicine Newsletter in which a prohibition of veterinarian staff dispensing in the absence of the veterinarian was detailed.

Chris Greiner, of Supervalu Pharmacies presented a request for rule promulgation regarding the annual inventory of stocks of controlled substances. After much debate, the Board will initiate rule promulgation, allowing the annual controlled substance inventory to be conducted within 7 days of the prior year's inventory date.

Dr. de Blaquiére called for Public Comment. There was no public comment.

Dr. de Blaquiére called the meeting to order after a lunch break.

Mr. Snook presented BOP case number 07-65, reinstatement hearing regarding the order for termination of probation in the matter of Janet Stickler. Ms. Stickler previously voluntarily surrendered her pharmacist license and controlled substance registration on September 28, 2007. On October 26, 2007, the Board entered a stipulation and order suspending Ms. Stickler's pharmacist license and controlled substance registration for a minimum of one (1) year, mandated treatment & recovery programs, and a four (4) year probation period, should reinstatement of licensing be approved by the Board. On December 17, 2008, the Board entered a stipulation and order reinstating Ms. Stickler's pharmacist license and controlled substance registration, with a four (4) probation period. On or about March 13, 2012, Ms. Stickler submitted a written request to the Board office requesting early release from probation. On or about April 18, 2012 the Board office received a letter from Southworth Associates, administrator of the Board's pharmacy recovery network (PRN) supporting Ms. Stickler's request for the early termination of Ms. Stickler's probation order. Ms. Stickler has maintained an active recovery for nearly five (5) years and has complied with terms of the probation order. After

Board discussion Dr. Henggeler motioned to accept the order to terminate the probation order. Dr. Chopski seconded. The motion passed unanimously.

Mr. Snook represented the Board in a hearing regarding BOP case number 11-727-A, administrative complaint in the matter of Mark Coburn, R.Ph, involving violations of Idaho Code 54-1726(a)(f), and rule 184.04, 251.03(a) for mis-filled prescriptions on June 20, 2011 & on July 28, 2011. Dr. de Blaquiére recused himself. As presiding officer, Mr. Fraser called the hearing to order. Mr. Coburn participated in the hearing in person, without legal counsel. Considering the onsite investigation, Mr. Coburn's explanation and remedies, the Board staff has recommended that Mr. Coburn pay a fine of one thousand (\$1,000.00) dollars, and to complete twelve (12) continuing education credits on pharmacy safety within one hundred and eighty (180) days. Dr. Henggeler motioned to accept the Board staff recommendation. Mr. Sperry seconded. The motion passed unanimously.

Mr. Snook presented BOP case number 11-727-B, stipulation and consent order in the matter of Jamie Jeffres, pharmacy technician, involving violations of Idaho Code 54-1726(a)(f), and Board rule 184.04. Ms. Jeffres worked with Mark Coburn, R.Ph and assisted with and/or participated in the mis-filling of a prescription on June 20, 2011. The stipulation and consent order indicates that Ms. Jeffres is to pay a two hundred and fifty (\$250.00) dollar fine and complete four (4) credits of continuing education pertaining to prescription and/or medication error within ninety (90) days. Dr. Chopski motioned to accept the stipulation and order as written. Dr. Henggeler seconded. The motion passed unanimously.

BOP case number 11-817-B was vacated.

Mr. Snook presented BOP case number 12-015, default order case in the matter of Jennifer LaPlante. On April 16, 2012, Mr. Snook filed an affidavit from Mark Johnston supporting default. Mr. Johnston then issued a Notice of Appointment of Hearing Officer, designating Jenifer Marcus, DAG as the hearing officer. Mr. Snook provided Ms. Marcus with a Notice of Proposed Default Order and a Default Order. On April 26, 2012, Ms. Marcus sent the Notice of Proposed Default Order and the Default Order to the respondent who had seven (7) days to contest entry of the Default Order. There was no response from the respondent. Ms. Marcus entered into Default Orders and Mr. Snook presented proposed Findings of Fact, Conclusion of Law and a Final Order, based upon default, to the Board for consideration. Dr. Chopski motioned to accept the finding of fact, conclusion of law, and final order. Mr. Fraser seconded. The motion passed unanimously.

Mr. Snook represented the Board in a request for reinstatement hearing regarding BOP case number 12-018, in the matter of Mr. Andrew Welch, Pharm D. Mr. Welch participated in the hearing in person. Mr. James A 'Drew' Pendlebury, legal counsel for Mr. Welch participated via telephone. Mr. Welch's pharmacist license and controlled substance registration were emergency suspended on January 11, 2012. Mr. Welch did not present any new information regarding the events that led to the emergency suspension. Mr. Snook introduced redacted copies of documents that were obtained during the Boards continued investigation of Mr. Welch's case. The documents were labeled Exhibits A-1 through A-6. Exhibit A-1 was a letter from Donald M. Levin, DO, and exhibits A-2 through A-6 contained lists of dispensed prescription medications that were filled by Mr. Welch, for Mr. Welch, and several of his family members. The exhibits indicate that Mr. Welch dispensed several hundred prescription medications without a valid prescription. Due to advice from his legal counsel Mr. Welch did not provide a statement regarding the dispensed prescription medications. Dr. Chopski motioned to deny reinstatement based on lack of information. Dr. Chopski withdrew her motion to allow

further statements per hearing protocol. After further discussion and closing comments, Dr. Chopski motioned to deny reinstatement based on lack of information. Mr. Fraser seconded with discussion. After Board discussion a vote was called and the motion passed unanimously.

Dr. de Blaquiére called the meeting back to order after a short break.

Mr. Snook presented BOP case number 12-016, stipulation and consent order for Brian Chambers, R.Ph, involving violations of Idaho Code 37-2722(a)(c), 54-1726(a)(f), and Board rule 184.07 & 184.08, for the diversion of controlled substances from Mr. Chambers' employer. Dr. Henggeler recused herself. After Board discussion Dr. Chopski motioned to accept the stipulation and order as written. Mr. Fraser seconded. The motion passed unanimously.

The Board directed Mr. Johnston to require pharmacists who stipulate to PRN contract adherence should either appear when the Board initially approves of the stipulated order or during a reinstatement hearing.

Mr. Snook presented BOP case number 10-048, request for modification of Board order for Alan Maxwell, R.Ph. Mr. Maxwell was not present. Mr. Maxwell requested the elimination of required monthly audits by his employer, as ordered by the Board on 10/28/2010. Dr. Chopski motioned to reduce the monthly audit requirement to quarterly. Dr. Henggeler seconded. After discussion, Dr. Chopski withdrew her motion, so that Mr. Maxwell's request could be addressed first. After Board more discussion, Dr. Henggeler motioned to deny the request and then to reduce the audit requirements to quarterly. Dr. Chopski seconded. A vote was called and the motion passed unanimously.

During public comment Nichelle Daigle, recent ISU College of Pharmacy graduate, approached the Board regarding her pharmacist application. Ms. Daigle received a withheld judgment for two non-drug related felonies while still in pharmacy school. After a lengthy Board discussion, Mr. Sperry motioned Ms. Daigle submit to the Board staff all supporting documentation to include psychological reports, probation reports, arrest record and anything else that the Board staff would need to review her case, delegating authority to Mr. Johnston to approve Ms. Daigle's application, if all seemed in order. Mr. Fraser seconded. The motion passed unanimously.

Mr. Johnston presented the Board's financial report:

- Comparisons of budget to expenses indicate that 90% of the fiscal year is completed & approximately the same percentage of the budget has been utilized.
- The Board office is engaged in zero based budgeting with the hopes of proving that operating dollars could be moved to personnel to consider requesting a Customer Service Representative position.
- Regarding the 2012 controlled substance renewals;
 - 5.5% of the registrants didn't renew.
 - 89% renewed online
 - 1% renewed late

Mr. Johnston presented the travel calendar. Mr. Johnston & Mr. Sperry attended the Annual NABP meeting from May 19th through May 22nd, in Philadelphia, PA. Dr. Chopski attended the ASCP Spring Conference meeting from May 21st through May 23rd, in Anaheim, CA. Mr. Johnston will present at the NW Pharmacy Convention on June 3rd in Coeur d'Alene, ID. Mr. Johnston, Mr. Fraser and Dr. Chopski will attend the Northwest Pharmacy Convention. Mr.

Johnston and Teresa Anderson, Program Information Coordinator Idaho Prescription Monitoring Program will attend the Alliance of States with Prescription Monitoring Programs National meeting on June 3rd through June 6th in Washington, DC. Mr. Johnston will be on vacation from June 8th through June 25th. The next Board meeting will be on August 21st & 22nd, in Boise, ID at the State Capitol. Mr. Johnston is contemplating attending the NACDS conference August 25th through August 28th, in Denver, CO. Mr. Johnston will be attending the NABP Executive Committee meeting September 17th & 18th, in Chicago, IL. Ms. Anderson will be attending the Regional Alliance of States meeting September 18th & 19th, in Boise, ID. Mr. Johnston, and possibly Mr. Fraser and/or Dr. Chopski will attend the NABP Interactive Member forum on September 19th & September 20th, in Chicago, IL. Mr. Johnston will teach a law class at the ISHP Fall meeting on September 30th, in Sun Valley, ID. Mr. Johnston will take vacation from October 9th through October 12th. Mr. Johnston is contemplating attending the Tri Regulator symposium on October 17th & 18th, in Washington, DC. Mr. Johnston and Dr. Chopski will attend the NABP District meeting from October 21st through October 24th, in Little Rock, AR. Ms. Anderson will attend the NASCSA meeting from October 22nd through October 26th, in Scottsdale, AZ. The ISU Dean's Advisory committee will be on October 27th, in Pocatello, ID. The fall Board meeting will be held on November 2nd, in Boise, ID. Mr. Johnston will attend the NABP Interactive Executive Officers forum on November 13th & 14th, in Chicago, IL. Mr. Johnston and Dr. de Blaquiére will attend the ASPL meeting from November 15th through November 18th, in Tucson, AZ. The Board scheduled a conference call on July 26th, at 8:00 am.

As requested by Dr. Chopski at the last Board meeting, Mr. Johnston presented a list of delegated authority that was granted to the Board's staff during the last six (6) years. Mr. Johnston requested delegated authority regarding remodels in a pharmacy to temporarily waive the restroom requirement. The Board agreed via unanimous consent.

During Inspector Q & A Mr. Johnston summarized the results of the Inspector Workshop that took place April 9th through April 12th, at the Board office. Several applications were modified and new inspection forms were created.

Mr. Johnston presented a duplication of assuring public safety by both the Board of Pharmacy and the Bureau of Facility Standards/Department of Health, as both are inspecting Nursing Homes. The Board agreed that the Board should stop inspecting Nursing Homes.

Mr. Johnston introduced the Boards new legal counsel, Nicole McKay, DAG and prosecuting counsel Kathy Takasugi, DAG. Ms. McKay will also be assisting in the rewriting of the Boards statutes. At the conclusion of the Board meeting Jennifer Marcus, DAG and Mr. Snook will move onto other assignments.

Mr. Johnston presented draft rules regarding InstyMeds 4/5/12 requested rule changes. The Board instructed Mr. Johnston to clarify that such self service ADS systems are to be restricted for a hospital's emergency room use only and not the remainder of the hospital, to limit controlled substances to a 24 hour supply, to restrict reconstituted products from inclusion, to require counseling before dispensing, and to clarify that such systems can only be used in a geographically restricted area. Due to time constraints the remaining portion of the legislation and rule review agenda item was vacated.

Dr. Henggeler motioned that Mr. Fraser become Board Chair. Dr. Chopski seconded. The motion passed unanimously.

Mr. Fraser motioned that Dr. Chopski become Vice Chairman. Dr. Henggeler seconded. The motion passed unanimously.

Mr. Johnston requested that the Board extend the deadline regarding the Idaho Wholesale Drug Distribution Act that mandates electronic track and trace technology. Electronic track and trace is still not widely available, and Mr. Johnston is aware of no other state that requires it. Extensions have been previously approved in the years 2008 through 2011. Mr. Johnston requested that the Board extend the deadline by one (1) more year. The Board agreed via unanimous consent.

Mr. Fraser motioned to adjourn. Dr. Henggeler seconded. The motion passed unanimously. The meeting ended at 5:47 pm.